

### **REMARKS/ARGUMENTS**

Claims 1, 3, 17-20, 25, 26, and 81-85 have been amended. Claim 13 has been cancelled from the application. Claims 29-80 were previously cancelled. Claims 1-12, 14-28 and 81-85 are pending in the application.

#### **Claim Rejections under USC 35 §112**

Claim 1 was amended to comply with the written description requirement. The claim no longer makes reference to any connector, but now recites a “valve” for which clear written description is found in the specification as originally filed. The rejection is therefore believed overcome and favorable reconsideration of the amended claim is respectfully requested.

#### **Claim Rejections under USC 35 102(b)**

The Examiner has rejected claims 1-9, 13-14, 21, 24-28, 81, 83 and 84 under 35 USC 102(b) as being anticipated by the teachings of Stiene (WO 02/49507). Applicant respectfully submits that the amended claims submitted herewith define subject matter clearly distinguished from Stiene.

Amended claims 1, 3 and 81-85 clearly define inventive subject matter not taught in Stiene. As stated in detail in applicant's response to the previous Office Action, the invention is directed to an injector pump for pushing an aqueous injector fluid included in the pump to a downstream injector fluid receiving location. The injector fluid pumped is not a sample fluid of unknown composition, for example fluid collected from a patient, but a known fluid incorporated into the pump prior to pushing of the injector fluid to the downstream location. All independent claims have been amended to clarify the difference between the injector fluid and a sample fluid. Furthermore, the downstream device has been defined as a sample fluid analysis device and the downstream location as a sample fluid flow path of the analysis device. Stiene neither teaches nor suggests an injector pump for a downstream sample fluid analysis device. In contrast, Stiene discloses a sample collection and analysis device. Pumping of the sample fluid by way of a separate injector fluid is not disclosed. Neither is the adding/flushing of reagents to or from the sample fluid by way of an injector fluid pushed by an injector fluid pump. The independent claims have further been amended to define the injector fluid reservoir as being integral to the pump and to recite the feature of the valve which

maintains the injector fluid in the reservoir and allows for selective opening of the reservoir to release the injector fluid from the reservoir. Stiene neither discloses nor suggests a pump including an integral injection fluid filled reservoir and a valve for selectively releasing the fluid from the reservoir.

The principle of the injector pump of the invention is to electro-osmotically pump an integral injector fluid of known consistency to generate a head pressure for the downstream pumping of another fluid in the downstream device. The integral injector fluid, or pump priming fluid is used as a hydraulic pushing fluid for the pumping of other fluids in the downstream device. This allows, for example, for the pumping of a sample fluid without having to expose the sample fluid to an electrical potential, which may be disadvantageous. The use of an upstream injector pump with integrated pushing or priming fluid also overcomes the problems inherent with the electro-osmotic pumping of physiological fluids. As will be appreciated by the skilled person, the direct eletro-osmotic pumping of physiological fluids may require the use of high voltages, which could result in damage to components in the sample fluid. Moreover, the voltage needed for pumping physiological fluids depends on the ionic strength of the fluid, which will of course vary from sample to sample. By using an upstream injector pump with an integrated priming fluid of known consistency, the embodiments of the present application are able to hydraulically pump downstream liquids of completely unknown consistency and completely avoid the need to expose a sample fluid to an electrical potential. This is clearly neither taught nor even suggested in Stiene. Thus, the amended claims are distinguished from the cited reference and acceptable under USC 35 102(b). Favorable consideration of the amended claims is respectfully requested.

The Examiner has stated that Stiene teaches an apparatus which includes the patient as a reservoir for an aqueous injector fluid. Applicant respectfully objects to the Examiner's interpretation of the cited reference. Stiene neither teaches nor suggests that the patient be incorporated into the apparatus or that the patient form the injection fluid reservoir of the apparatus. To clarify the fact that the reservoir is actually part of the pump as claimed and not a separate item or living being, the independent claims now define the reservoir as integral to the pump. Thus, the Examiner's interpretation of the Stiene reference no longer applies, since Stiene clearly does not disclose an apparatus with an incorporated patient.

Stiene discloses a sample fluid (blood) collection and analysis device. Stiene makes no mention whatsoever of any injector fluid separate from a sample fluid to be analyzed. All fluids collected in and pumped within the apparatus of Stiene are sample fluids to be analyzed, which means fluids of unknown composition, and not injector fluids of known composition.

In summary, Stiene neither discloses nor suggests a pump for pushing an injection fluid to a fluid sample flow path of a fluid sample analysis device. Stiene furthermore fails to teach an injector pump which includes an integral, injection fluid filled reservoir and a valve for selectively releasing the fluid from the reservoir. Moreover, Stiene fails to disclose a pump wherein the injection fluid released from the integral reservoir by way of the valve is released into a microporous fluidic path fluidically separated from the fluid sample flow path of the analysis device by an isolator to maintain the injector fluid in the fluidic path until it is electro-osmotically pumped across the insulator. Therefore, Stiene cannot anticipate the subject matter of the claims as amended and withdrawal of the Examiner's rejection under USC 35 102(b) is respectfully requested.

#### **Claim Rejections under USC 35 §103(a)**

The Examiner has rejected claims 10-12, 15-20, 22-23 and 82 under 35 USC 103(a) as being obviated by Stiene in view of U.S. Patent No. 6,013,164 to Paul.

Applicant respectfully submits that the claims submitted herewith all define subject matter patentably distinguished over the references cited by the Examiner.

As mentioned above, the claims of the present application are directed to an injector pump with an integral injector fluid or priming fluid reservoir and a valve for selectively releasing the injector fluid from the reservoir, subject matter not at all disclosed in Stiene. Moreover, Paul also fails to disclose an injector pump with the particular features defined in the amended claims. Therefore, applicant respectfully submits that even the combined teachings of Stiene and Paul would not lead the art skilled person to the injector pump structures of the present invention.

The Examiner has rejected claims 17 and 18 under 35 USC 103(a) as being obviated by Stiene in view of Paul. It is the Examiner's position that it would have been obvious to the ordinary skilled person to provide an integral fluid reservoir. Applicant strongly disagrees. Stiene teaches a fluid sample (blood) collection and analysis device. The sample is collected from the patient for analysis. Clearly, incorporating the patient into the device to embody the reservoir would never be an obvious solution. Also, incorporating a fluid sample reservoir into the apparatus of Stiene would neither maximize the efficiency of the device, nor would the resulting apparatus have any structural or functional resemblance to the pump defined in the claims as presently amended. An apparatus according to Stiene including an integral sample fluid reservoir would still not include any injector fluid reservoir, nor any valve for selectively releasing the injector fluid stored in the integral reservoir. This deficiency can also not be overcome on the basis of the teachings of Paul. Therefore, applicant respectfully submits that even the combined teachings of Stiene and Levy would not lead the art skilled person to the injector pump structures of the present invention.

#### **Allowable Subject Matter**

The Examiner has previously identified claims 3-9, 14-16 and 28 as being directed to allowable subject matter. Claim 3 has been rewritten in independent form to include all of the limitations of original claim 1 from which it previously depended. Thus, claim 3 and claims 4-9, 14-16 and 28 depending therefrom are believed to be in allowable condition. Should the Examiner's opinion as to the patentability of the subject matter of original claim 3 have changed, applicant respectfully requests the Examiner to state the reasons why.

#### **Conclusion**

Applicant respectfully submits that the amended independent claims 1, 3 and 81 to 85 submitted herewith and all claims dependent therefrom now define subject matter patentably distinguished over the references cited by the Examiner.

Applicant submits that the application is now in condition for further examination and awaits further action.

Appl. No. 10/649,683  
Amdt. dated October 22, 2008  
Reply to Office Action of July 22, 2008

The Commissioner is hereby authorized to charge any additional fees, and credit any over payments to Deposit Account No. 501593, in the name of Borden Ladner Gervais LLP.

Respectfully

**LAUKS, Imants et al.**

/Shin Hung/

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